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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,637	03/15/2002	Gerardo M. Castillo	PROTEO.P16CI	4148

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EXAMINER	
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ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,637	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/19/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Examiner's Note

The examiner respectfully points out that the current claim set of 9/29/2005 lists claims 12 and 13 as "currently amended". The previous claim set of 1/13/2005 is identical to the current claim set including the listing of claims 12 and 13 as "currently amended". The examiner points out that claims 12 and 13 of both claim sets do not indicate how the claims have been amended and thus are not in compliance with the requirements of 37 CFR 1.121. As the previous examiner has acted on the merits of the claim set, the claims will be considered based on their merits. The examiner respectfully requests that all further amendments to the claims be in accord with the requirements of 37 CFR 1.121.

Status of Claims

The examiner notes the receipt of the applicant's remarks on 9/29/2005 amending no claims and presenting arguments against the 35 USC 102(b) rejection of claims 9-15 and 17. Claims 9-15 and 17 are currently pending. The rejection of claims 9-15 and 17 is maintained for reasons set forth below in the response to arguments. The 102(b) rejections and obviousness-type double patenting rejection of claims 9-15 and 17 are reproduced below.

The applicant's state on page 8 of the remarks that an appropriate terminal disclaimer will be filed upon indication of allowable subject matter. The obviousness-type double patenting rejection is thus maintained until the terminal disclaimer is filed.

Response to Arguments

Applicant's arguments filed 9/29/2005 have been fully considered but they are not persuasive.

The applicant's state on page 4 of the remarks: "The disclosures of Kuznicki are not directed to therapeutics for diseases of any sort." Without admitting to the applicant's assertion, the examiner respectfully points out that the "disclosures of Kuznicki" utilized as prior art are drawn to compositions. As the applicant's claims currently under consideration are drawn to compositions as well the use of Kuznicki's prior art compositions is relevant and appropriate.

The applicant's assert on pages 4-5 of the remarks that claim 17 is especially distinguished over the prior art as it uses the closed language of "consisting of" in lieu of the open language of "comprising of" of the previous claims. The claim reads "...consisting of a therapeutically effective amount of catechin and of a pharmaceutically carrier, diluent or excipient...". The insertion of pharmaceutically carrier, diluent or excipient means that there is a plurality of components that can be included in the composition. The applicant asserts that the examiner's characterization of fruit juice, flavoring, sodium citrate and the like as excipients is a stretch beyond any common understanding of the meaning of the term excipient as it is used by those of ordinary

skill in the art. The examiner respectfully disagrees. The term excipient is defined in Churchill's illustrated Medical Dictionary (1989) page 658 as: "A pharmacologically inactive substance which is combined with a drug to confer a suitable physical form to the mixture and facilitate the administration of the drug". The definition does not exclude fruit juice, flavorings, etc... and indeed would include them in the formulation of drugs especially in the formulation of drugs for use by infants and children where fruit juice and flavorings are commonly added to make the drugs more palatable. As "beverage enhancements" can be considered excipients, claim 17 is correctly rejected.

The applicant's state on page 5: "The examiner asserts that Mitsui discloses the same ingredients, but Mitsui discloses no therapeutic efficacy for anti-fibrillogenesis, and therefore can not be regarded as disclosing the same ingredients." The examiner respectfully points out again that the present claims are to compositions and not methods. The fact that Mitsui's compositions are not directed toward anti-fibrillogenesis is of no concern. The compositions are identical and thus anticipated by Mitsui's compositions. Perhaps the applicant's would better understand the problem with this argument with a different example. Instead of "the same ingredients" as stated in the applicant's assertion use "aspirin" in its place. The applicant's assertion would then read as follows: "The examiner asserts that Mitsui discloses *aspirin*, but Mitsui discloses no therapeutic efficacy for anti-fibrillogenesis, and therefore can not be regarded as disclosing *aspirin*."

As the inherency arguments are based upon the "consisting of" and "excipient" and "diluent" aspects of claim 17 and have been addressed above, no further elaboration is warranted.

The applicant's state on page 8 of the remarks that an appropriate terminal disclaimer will be filed upon indication of allowable subject matter. The obviousness type double patenting rejections are maintained and reproduced below.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681 ,569) for reasons of record stated in the Office Action dated July 13, 2004.

Kuznicki et al. discloses a composition comprising 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, cbl.2, lines12-14: Example 1, 11, and 111 at col.10, and claims 1 and 5-6.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (1t-loomg/kg of body weight of the subject), is disclosed in the Example I and 111 (see col. 10 lines 1-41) as shown in the calculation below:

Example 111 discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example 1, the effective amount of catechins (or flavanols)

= 83% X 0.097% (see col.10 line 15 in particular) = 0.8099 g = 809.9 mg

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

= 835g X 0.35/100 X 29/100 = 0.8475 g = 847.5 mg.

Since a standard person weight is 70 kg, the range of effective amounts of catechins is 10 mg/kg X 70 kg =700 mg to 1000 mg/kg X 70 kg = 70.000 mg.

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the ad (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses

that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

Thus, Kuznicki's composition inherently treat amyloid in a mammal. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Thus, Kuznicki et al. anticipates claims 9-15 and 17.

Claims 9, 12-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 for reasons of record stated in the Office Action dated July 13, 2004.

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by b-amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts (doses) of diminishing the toxicity of p-amyloid protein (see particularly page 1 the 2nd paragraph, claims 1-3 at page 1., page 2 (0001), (0002)), and a pharmaceutical carrier (i.e., water). See also page 7 (0028), page 8 (0029). JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 (0027)). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, JP 10245342 anticipates claims 9, 12-15, and 17.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9-11 of the copending Application No. 10/762,444.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a drug product for treating amylodosis in a mammal comprising a composition a compound of Formula E which is epicatechin (see Fig. 1 B herein) and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin and pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/762,444.

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13'of the copending Application No. 10/610,349.

Although the conflicting claims are not idéntical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas.The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin present in green teas and pharmaceutically acceptable excipients in effective amounts within the copending Application. Therefore, one of ordinary skill in the ad would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,349.

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of the copending Application No. 10/610,346.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas. The claim of the instant application is drawn to a

pharmaceutical composition for treating the same comprising epicatechin present in green teas and a pharmaceutically acceptable excipients in effective amounts within the copending Application claim. Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,346.

Above obviousness-type double patenting rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER